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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,964

09/29/2003

Osmond D'Cruz

12152.9USC3

5285

23552 7590 01/17/2007  
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.	Applicant(s)	
10/674,964	D'CRUZ ET AL.	
Examiner	Art Unit	
San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☒ Claim(s) 21-26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-12-04</u> | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

This application is the continuation application of 10/222,594, filed 08/15/2002, now US PAT 6,627,655, which is a continuation application of 09/457,247, filed 12/08/1999, now US PAT 6,500,860, which is a Divisional application of 09/008,898, filed 01/20/1998, now US PAT 6,051,603.

Claims 17-26 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the organometallic cyclopentadienyl complexes of vanadium IV disclosed in the specification, pages 5-6, does not reasonably provide enablement for other organometallic cyclopentadienyl complexes of vanadium IV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have

required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to provide information allowing the skilled artisan to ascertain these compounds possessing the recited, and claimed, physiological activity without undue experimentation.

- 1) the quantity of experimentation necessary,

. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all organometallic cyclopentadienyl complexes of vanadium IV, necessitating an exhaustive search for all embodiments, regardless their chemical formula, or structure, suitable to practice the claimed invention. Examiner notes the claims read on all compounds possessing the envisioned partial structure of the complexes, disclosed , or undisclosed, regardless the other structural formula of these compounds. Additionally,

those compounds seen as encompassing such physiological activity must be experimentally discovered by the skilled artisan.

2) the amount of direction or guidance provided,

In the instant case, only a limited number of organometallic cyclopentadienyl complexes of vanadium IV examples are set forth, thereby failing to provide sufficient working examples. Those compounds disclosed in the instant specification encompass only a small number of those compound classes envisioned as possessing physiological activity required to practice the invention as herein claimed. Absent that small genus of compounds herein recited, the instant specification is silent as to making, or using, those other compound genera encompassed by the instant claims. Although the specification directs the skilled artisan to specific organometallic cyclopentadienyl complexes of vanadium IV such as VDBPY, VDPH, VDH, etc., the application is silent with regard to selection of any additional compounds structurally unrelated to those few compounds listed in the instant specification.

3) the presence, or absence, of working examples,

Applicant fails to set forth the criteria that structurally defines, or identifies, those compounds possessing organometallic cyclopentadienyl ligands of vanadium IV complexes. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of organometallic cyclopentadienyl complexes of vanadium IV examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define those structural classes of

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compounds required to practice the invention as herein claimed, as required by those guidelines set forth in *In re Wands*, supra. Absent exemplification providing guidance as to these compound classes herein envisioned, the instant specification fails to place those compound classes possessing various structural formulas requiring selective testicular germ cell killing activity in the skilled artisan's possession, absent undue experimentation.

4) the nature of the invention,

The instant invention reading on all possible compounds possessing the selective testicular germ cell killing activity having the cyclopentadienyl moiety envisioned, disclosed, or undisclosed, set forth a broad inventive scope. Claims herein presented require all compounds, regardless of structural formula of other ligands in the complexes, suspected of possessing the instant recited selective testicular germ cell killing activity to be assayed individually for their suitability in practicing the invention herein recited.

5) the state of the prior art,

The instant claims read on all organometallic cyclopentadienyl ligands of vanadium IV, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Although various individual compounds possessing the disclosed selective testicular germ cell killing activity are known to those of skill in the art, no information is provided to guide the skilled artisan to those diverse genera of structurally divergent complexes possessing similar physiological activity. Examiner is unaware of any nexus, stated in the art, or herein disclosed, attributing the herein

envisioned physiological activity to one, or another, structural formula. In fact, in Ghosh et al., Journal of inorganic Biochemistry, 1998;72:89-98, discloses other vanadium IV salts did not elicit any spermidical activity against membrane-intact sperm even at the millimolar concentration (See page 97, col. 1, last paragraph). It is clear that not any complexes of vanadium IV will have the envisioned sperm cell killing activity. Simply stated the skilled artisan must employ experimentation to discover compounds possessing the selective testicular germ cell killing activity required to practice the claimed invention.

6) the relative skill of those in the art

Those individuals skilled in the art possess the required knowledge to perform those assays employed to identify compounds useful for practicing the invention as herein claimed. Applicants' failure to provide adequate guidance as to the envisioned structural formulas employed in the instant claims requires the skilled artisan to establish, by individual assay, each compound deemed suitable for use in the instant invention.

7) the predictability of the art,

The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. With the mechanism of selective killing the sperm cell is unknown, the skilled artisan must test each compound against the envisioned biochemical lesion to determine the possible use of such compounds in the instant invention.

8) the breadth of the claims.

. The instant claims read on all "organometallic cyclopentadienyl ligands of vanadium IV", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Examiner notes the instant claims fail to provide any guidance as to those structural embodiments inherent in those compounds possessing the selective testicular germ cell killing activity herein envisioned. Applicant's claims encompass every, and all, compounds providing the recited selective testicular germ cell killing activity regardless the structural formula of such compounds. Absent guidance with regard to the structural identifies of those compounds possessing the recited selective testicular germ cell killing activity, each compounds must be identified by experimentation in every case. Applicants fail to provide information sufficient to identify the structural formulas of those compounds useful to practice the claimed invention, absent undue experimentation.

***Allowable Subject Matter***

Claims 21-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

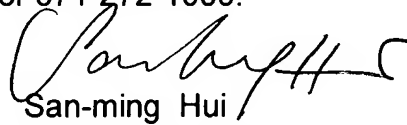
Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax



phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
San-ming Hui  
Primary Examiner  
Art Unit 1617